

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING  
PHARMACY, INC. PRODUCTS  
LIABILITY LITIGATION

MDL No. 13-2419  
Dkt. No 1:13-md-2419 (RWZ)

THIS DOCUMENT RELATES TO:

## All Cases Against the Saint Thomas Entities

**BRIEF OF DEFENDANTS SAINT THOMAS HEALTH, SAINT THOMAS  
NETWORK, AND ST. THOMAS HOSPITAL IN SUPPORT OF  
MOTION FOR RELIEF AS TO PROPOSED BELLWETHER TRIALS**

## TABLE OF CONTENTS

Introduction.....	1
Argument .....	2
I. The MDL Remand Process Cannot Be Resolved in Time for a Summer Trial.....	2
II. The Criminal Case Against the NECC Insiders Should Be Tried First.....	3
A. The Court Has Previously—and Correctly—Found Substantial Overlap in These Proceedings .....	4
B. The Delay Would Be Brief, But Critically Important to Finding the Truth .....	6
C. If Civil Trials Proceed First, There Is a Significant Risk That the Criminal Prosecution Could Be Adversely Impacted .....	7
D. The Criminal Discovery Is Needed For Fair Adjudication of Civil Liability.....	11
E. Trying the Criminal Case First Eliminates Both the Risk to the Government and Prejudice to the Saint Thomas Entities .....	14
F. The Public Interest and Judicial Economy Are Served by Sequencing the Criminal Trial First .....	15
G. This Request Is Made in Good Faith .....	16
H. The Status of the Cases Favors Deferral.....	17
III. The Bellwether Schedule Proposed by the Court Is Overly Ambitious .....	17
A. There Is Not Enough Time for Ruling on Daubert and Case-Specific Dispositive-Motion Challenges .....	17
B. Neither the Court Nor the Parties Can Accommodate Four Back-to-Back Bellwether Trial Settings .....	17
C. Both Common-Issue and Case-Specific Discovery Is Ongoing .....	18
IV. The Tennessee Court Should Make any Trial Settings.....	19
A. Recent Developments Confirm These Cases Should Be Tried in Tennessee.....	19
B. The § 157(b)(5) Considerations Weigh in Favor of Sending These Cases Back to Tennessee for Trial .....	19
Conclusion and Prayer .....	21

**TABLE OF CONTENTS**

(continued)

**Page**

Certificate of Service .....	23
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## INTRODUCTION

The Saint Thomas Entities<sup>1</sup> file this memorandum in support of their motion seeking various forms of relief related to the Court's announcement of its intention to try the first four bellwether cases involving plaintiffs with claims against the Nashville Healthcare Defendants<sup>2</sup> ("Tennessee Plaintiffs") beginning in July 2016. The cases cannot be ready for trial by that time even under the most optimistic view.

First, the Court has set out a remand procedure to transfer these cases back to Tennessee under the MDL statute<sup>3</sup> that requires action by the Judicial Panel of Multidistrict Litigation ("JPML") and the Middle District of Tennessee before retransfer to Boston can occur. It has also outlined issues as to standing and capacity that need to be addressed in order to consider whether the bankruptcy statute permits that action.<sup>4</sup> There is no way to expedite a process that requires participation by multiple courts and parties, and the process is not slated to begin before mid-June.

Second, the NECC Insiders'<sup>5</sup> criminal trial has been definitively set for September 8, meaning that if the civil trials go forward in July, critical discovery from NECC and its former employees and affiliates ("NECC Witnesses") and the U.S. Food and Drug Administration ("FDA") will not be available to the Nashville Healthcare Defendants, which will impede their ability to present their defense and to show the jury what truly happened. The Court's prior order expressly contemplated that the Nashville Healthcare Defendants would be entitled to take the

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<sup>1</sup> Saint Thomas West Hospital, formerly known as St. Thomas Hospital ("Hospital"), Saint Thomas Network ("Network"), and Saint Thomas Health ("Health") (collectively, the "Saint Thomas Entities").

<sup>2</sup> The "Nashville Healthcare Defendants" are the Saint Thomas Entities, as well as Saint Thomas Outpatient Neurosurgical Center, LLC ("STOPNC"), Howell Allen Clinic, P.C., John Culclasure, M.D., Debra Schamberg, RN, CNOR, and Vaughan Allen, M.D.

<sup>3</sup> 28 U.S.C. § 1407.

<sup>4</sup> 28 U.S.C. § 157(b)(5).

<sup>5</sup> The "NECC Insiders" are entities and individuals affiliated with NECC, including Barry and Lisa Cadden; Doug, Carla, and Greg Conigliaro; Glenn Chin; Alaunus Pharmaceutical, LLC; Ameridose, LLC; GDC Properties Management, Inc.; Medical Sales Management, Inc.; and Medical Sales Management, SW, Inc.

depositions of these parties after the criminal trial,<sup>6</sup> and that is a very different matter from forcing them to try these cases without this unquestionably relevant proof. Requiring the civil cases to be tried first risks avoidable, but adverse, consequences to the government's prosecution.

Third, the bellwether schedule initially proposed by the Court would not afford sufficient time for *Daubert* and dispositive motions, and each case is likely to take more than four weeks to fully try. Moreover, case-specific fact discovery is still ongoing, common-issue expert discovery is ongoing, and case-specific expert discovery has only just begun. There is much pretrial work to be done before the first bellwether trial can start despite the diligence of all counsel.

Fourth, the U.S. District Court for the Middle District of Tennessee should decide when to set the first four bellwethers for trial upon remand. Even if the Court has the authority under §157(b)(5) of the Bankruptcy Code to order retransfer to Boston for trial, it should decline to do so under the circumstances. These cases—now involving only Tennessee (and a few Kentucky) residents with healthcare liability claims against Tennessee healthcare providers governed by Tennessee law—should be tried before Tennessee juries in their home state, where the parties reside and many critical, third-party witnesses are subject to that court's subpoena power.

## ARGUMENT

### **I. The MDL Remand Process Cannot Be Resolved in Time for a Summer Trial**

The Court previously indicated that it will file a suggestion of remand with the JPML “after *Daubert* motions are fully briefed,” Docket #2309 at 22, having concluded the pretrial proceedings that involve common issues. Under the current trial schedule, the deadline for filing *Daubert* motions is May 27, 2016.<sup>7</sup> Taking into account the response period allowed under the local rules, the Court's suggestion of remand to the MDL panel would not be filed until mid-June—only days

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<sup>6</sup> Docket #2123 at 21.

<sup>7</sup> The *Daubert* motions cannot be filed earlier than May 27. Some Common-Issue Experts' depositions have not yet been taken or completed, and none of the Case-Specific Experts have been taken.

before any pre-trial conference would necessarily need to be held for the first bellwether trial. Once a suggestion of remand is filed with the JPML, a conditional remand order (“CRO”) is entered, but not sent to the transferor court for seven days so that parties receiving notice can file objections. *See* J.P.M.L. R. 10.2(a). Assuming that no party objects, the CRO is sent to the MDL court at which time it becomes effective. *Id.* 10.2(f). The parties will then stipulate or designate the record of items concerning each action remanded. *Id.* 10.4(a).

Once remanded, this Court will lose jurisdiction over the bellwether cases unless and until the § 157 issues are resolved in favor of the Court’s jurisdiction under the Bankruptcy Code and the cases are returned by the transferor court. And briefing will be necessary. For example, as the Court previously acknowledged, if the party moving to transfer venue is not the Post-Confirmation Officer (“PCO”), that party must address whether it is authorized by the bankruptcy statutes or rules to invoke § 157(b)(5). *See* Docket #2309 at 25 n.20. Only after that process is concluded can the § 157(b)(5) decision be made.

## **II. The Criminal Case Against the NECC Insiders Should Be Tried First**

The Court’s prior orders have curtailed or deferred discovery as to most of the NECC Witnesses and the FDA. *See, e.g.*, Docket ##2123, 2354, 2403.<sup>8</sup> Those orders contemplate that the Saint Thomas Entities will be able to obtain that evidence after the criminal trial. But those orders are nullities if the civil trials occur before the criminal trial concludes.

This Court has inherent and discretionary authority to stay civil actions for prudential reasons, including the co-pendency of a criminal trial. *Microfinancial, Inc. v. Premier Holidays Int’l, Inc.*, 385 F.3d 72, 77-78 (1st Cir. 2004). The First Circuit has observed several factors that typically inhere in such a decision:

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<sup>8</sup> In addition to the NECC Insiders, the government also moved to stay the depositions of Joseph Connolly and John Notarianni on grounds that they are potential witnesses in the criminal case. Docket ##2395, 2398. The Court granted the government’s motion. Docket #2556.

(i) the interests of the civil plaintiff in proceeding expeditiously with the civil litigation, including the avoidance of any prejudice to the plaintiff should a delay transpire; (ii) the hardship to the defendant, including the burden placed upon him should the cases go forward in tandem; (iii) the convenience of both the civil and criminal courts; (iv) the interests of third parties; [] (v) the public interest[] ... (vi) the good faith of the litigants (or the absence of it) and (vii) the status of the cases.

*Id.* The extent to which the criminal and civil proceedings overlap is often the most important consideration. *See, e.g.*, Docket #2123 at 15; *see also Sec. & Exch. Comm’n v. TelexFree, Inc.*, 52 F. Supp. 3d 349, 352 (D. Mass. 2014). Applying these factors, the Court should defer the civil actions until the criminal case is tried.

**A. The Court Has Previously—and Correctly—Found Substantial Overlap in These Proceedings**

There is substantial overlap between the criminal and civil cases. Docket #2123 at 15-16. That was the principal reason the Court denied the Saint Thomas Entities the right to take the NECC Witnesses’ depositions before the criminal trial. *Id.* In fact, the government agreed that “a stay would allow the civil defendants to avoid further substantial discovery costs while the criminal case proceeds.” Docket #2209 at 15.

The Court concluded that a blanket stay against deposing all but one of the NECC Witnesses was warranted because there were effectively no topics that the Nashville Healthcare Defendants could broach without implicating the Fifth Amendment: “[E]ven such apparently innocuous topics [as organizational structure, chains of command, and daily operations of NECC] might ‘furnish a link in the chain of evidence’ in demonstrating the Insider Defendants’ knowledge of and participation in the conduct giving rise to the criminal case.” Docket #2123 at 16 (quoting *Hoffman v. U.S.*, 341 U.S. 479, 486 (1951)). And the Court stayed the deposition of the FDA’s corporate representative because “any potential deposition would likely implicate, among other things, the investigatory steps taken by the FDA-OCI agents in the criminal case.” *Id.* at 21. There

is no question that the discovery being sought from the NECC Witnesses and the FDA, who have so far avoided it here, should be front and center in both proceedings.

As the government has asserted, NECC's clean rooms, quality control area, order-processing area, sales, regulatory history, and pre-and post-outbreak government inspections of NECC are plainly at issue in its criminal prosecution. *See, e.g.*, Docket #2209 at 11. These matters are also highly relevant to the civil cases because they bear on the PSC's ability to prove liability and causation. *See Saint Thomas Entities' Master Answer* [Docket #1464] at 52, 55-56 (pleading that they did not "proximately cause any damages alleged by Plaintiffs," which "are the consequence of independent, intervening, and superseding causes, and the acts of third persons," who "caused or contributed to cause the injuries" at issue and should be allocated fault); *see also Louria v. Brummett*, 916 S.W.2d 929, 930 (Tenn. Ct. App. 1995) (third party's criminal act is a superseding, intervening cause, which relieves a defendant of liability for negligence, when the criminal act is not reasonably foreseeable). And under Tennessee's comparative-fault law, the jury will apportion fault between the plaintiff, the defendants, and nonparties it concludes are at fault for the injury, *see* TENN. CODE ANN. § 20-1-119 (2015); *see also* Docket #1464 at 55-120,<sup>9</sup> which could eliminate or substantially reduce any liability assigned to these Defendants.

The opinions of the expert witnesses deposed to date demonstrate how the facts at issue in both proceedings are intermingled. The jury will be asked to consider the conduct of NECC and several others in causing each of the Bellwether Plaintiffs' damages:

- NECC failed to properly compound the MPA to eliminate the fungal contamination by, among other things, failing to autoclave the MPA according to the standards of United States Pharmacopeia ("USP") 797 and NECC's own written procedures, failing to terminally sterilize the MPA, and failing to conduct final product testing as also required by USP 797, which would have identified the contamination before it reached any patient.

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<sup>9</sup> The jury can also apportion fault to non-parties who might otherwise be immune from suit. *See Carroll v. Whitney*, 29 S.W.3d 14, 19 (Tenn. 2000).



- The fungus that contaminated the MPA entered the cleanroom from gaps in the ceiling grid that were misaligned by Liberty Industries at the time the cleanroom at issue was installed in 2006.
- ARL BioPharma, Inc. failed to perform USP 71 testing on each of the three lots of contaminated MPA.
- UniFirst Corporation, the company with sole responsibility for cleaning the walls and ceilings of the cleanroom where the MPA was compounded, failed to devote the time needed to properly clean, and failed to use proper cleaners or technique.
- The FDA and Massachusetts Board of Registration in Pharmacy failed to take appropriate action against NECC despite awareness that it was operating outside of the bounds of traditional pharmacy compounding.

The testimony outlined above is but some of the evidence of the actions and omissions of those who contributed to the Bellwether Plaintiffs' damages in this litigation, and it is vital to both the criminal and civil proceedings.

**B. The Delay Would Be Brief, But Critically Important to Finding the Truth**

The criminal trial commences September 8, 2016, and the Saint Thomas Entities are unaware of any reason for further delay. The PSC's "justice delayed" argument is not sufficient to show the kind of prejudice necessary to overcome the advantages of a brief delay of the civil trials. *See In re Adelpia Commc'ns Sec. Litig.*, 2003 WL 22358819, at \*4 (E.D. Pa. May 13, 2003) ("[C]ourts may insist that [the party opposing the stay] establish more prejudice than simply a delay in his right to expeditiously pursue his claim.").

Although the Tennessee Plaintiffs have a legitimate interest in getting these cases to trial as soon as possible, that interest has to be weighed against the prejudice to the Nashville Healthcare Defendants in having to defend themselves without critical evidence to support their case, as well as the public interest and judicial economy factors described below.

Moreover, the Court and the parties have means to mitigate "any prejudice to the plaintiff should a delay transpire," *Microfinancial*, 385 F.3d at 78. Specifically, the parties to the civil tort suits could be preparing the rest of the evidence and witnesses for trial and have access to the

criminal trial materials in real time so they could be ready to start trial shortly after the criminal trial is completed. To ensure no further delay, the Court could impose in advance a truncated timetable for the completion of discovery that is tied to the government resting its case in the criminal trial. Further, the PSC has reached a settlement of \$200 million with the wrongdoers, and many payments from the Tort Trust Fund have already been made to the MDL Plaintiffs, including the Tennessee Plaintiffs, which further mitigates against a brief delay of these civil trials.

It is entirely possible that the criminal trial could resolve—or at least provide a platform for agreed stipulations as to—some of the issues in this case in light of the considerable overlap between the cases. And the convictions of NECC’s ringleaders could be used in the civil case. *See* FED. R. EVID. 609 advisory committee’s note (“[E]vidence of conviction of crime is significant only because it stands as proof of the commission of the underlying criminal act.”).

In the alternative, if the Court will not entertain a brief delay, the Saint Thomas Entities request that the Court reconsider its prior rulings related to the NECC Witnesses and FDA to allow them to depose those individuals. The affected parties should be able to work out a protective order to allow access to the information, while satisfying the government’s confidentiality concerns.

**C. If Civil Trials Proceed First, There Is a Significant Risk That the Criminal Prosecution Could Be Adversely Impacted**

The overlap between the facts at issue in the civil and criminal trials presents a significant risk that the criminal prosecution could be adversely impacted if civil trials proceed first or at the same time as the criminal trial. Depending on how and why the contamination occurred, varying persons and entities will bear responsibility (civil and criminal). The NECC criminal defendants are seeking dismissal of the criminal charges on this very basis. *See U.S. v. Cadden*, No. 1:14-cr-10363-RGS [Docket #405] (claiming that the indictment against them fails, as the *government does not know how those vials got contaminated*, and it does not know what, if anything, Cadden

or Chin did to cause that contamination. .... *Such guesswork does not suffice to allege causation any more than it will suffice to prove it.* (emphasis added)).

Earlier in the civil MDL docket, the PSC and Saint Thomas Entities agreed on the source of contamination and the parties responsible for it: NECC, Liberty, Victory, ARL and UniFirst. In particular, the fungus had seeped through the ceiling that Liberty Industries improperly constructed and then failed to be removed by UniFirst's deficient cleaning services and Victory's inadequate pressurization scheme. ARL likewise failed to test sufficient sample sizes to catch the contamination. The PSC convinced the Court to deny Liberty's attempt at summary judgment on causation based largely in part on the sworn evidence it filed from Dr. Philip Austin, a licensed engineer and PhD.<sup>10</sup> Liberty subsequently settled with PSC, paying a million dollars into the Tort Trust Fund.<sup>11</sup> The PSC's aggressive stance likewise resulted in other substantial payments to the Tort Trust Fund of \$6.4 million by ARL, \$30.5 million by UniFirst and \$5.5 million by Victory.<sup>12</sup>

However, the PSC has now changed course. With millions of dollars in settlements pocketed, the PSC has filed a new expert report in which it now *contests* that the ceiling was the source of the contamination or that ARL, UniFirst, or Victory bear any responsibility whatsoever for the contamination.<sup>13</sup> In particular, the PSC's new expert witness for trial claims:

Therefore, it is my opinion, that *a causal connection between the actions of Liberty, Victory, UniClean or ARL cannot be drawn* to a reasonable degree of scientific certainty. Given the facts as presented, and as I understand them, it is my opinion that *it has not been demonstrated*, to a reasonable degree of scientific certainty, *that the actions of any of these vendors was a proximate cause of the contaminated MPA.*<sup>14</sup>

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<sup>10</sup> See PSC's Opposition to Liberty Industries, Inc.'s Omnibus Motion for Summary Judgment in Cases Filed by Plaintiffs Injected in Indiana [Docket #1610]; Memorandum of Decision [Docket #1613] (denying Liberty's motion for summary judgment and finding material issues of fact on causation for trial).

<sup>11</sup> See Liberty Settlement and Release Agreement, NECC Bankruptcy Case 12-19882 [Docket #1219-1].

<sup>12</sup> See NECC Disclosure Statement, NECC Bankruptcy Case 12-19882 [Docket #1181] at 91.

<sup>13</sup> See Report of Robert F. Guardino ("Guardino Report") (Exhibit A) at 3.

<sup>14</sup> See Guardino Report at 3.

This is of course directly opposite to the positions the PSC previously took before it collected the settlement monies from these parties.

The PSC's new position is particularly troubling given the statements made in their 2014 press releases trumpeting the initial \$100 million dollar settlement with NECC's owners and announcing its intention to go after the "other wrongdoers" such as Unifirst, Liberty and Victory for their "share of liability:"

"The job that we are *duty bound* to complete is far from over. We will continue with our efforts *to hold other wrongdoers accountable, including companies like UniFirst*, who was responsible for controlling contamination," Mark Zamora, a member of the Plaintiffs' Steering Committee said.

"We are hopeful that other national defendants currently engaged in the mediation program, *including the designer and installer of the cleanroom and HVAC systems*, will follow suit here and resolve *their share of liability* to increase compensation to the victims," said Kim Dougherty, another Plaintiffs' Steering Committee member.<sup>15</sup>

Now, in stark contrast, the PSC is defending these very wrongdoers—even going so far as to defend NECC's actions by suggesting there is not sufficient evidence that, for example, NECC's improper autoclaving was a cause of the contamination. In questioning one of STOPNC's common-issue experts, for example, the PSC now attempts to defend NECC's use of a 15-minute autoclave cycle,<sup>16</sup> which is one of the violations at issue in the criminal case.<sup>17</sup> In fact, the PSC is now arguing "it may never be known how and when the contamination occurred."<sup>18</sup>

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<sup>15</sup> See "Hagens Berman Announces \$100 Million Settlement for Victims in NECC Meningitis Outbreak" available at <http://www.businesswire.com/news/home/20140506007045/en/Hagens-Berman-Announces-100-Million-Settlement-Victims> (last visited Mar. 31, 2016) (emphasis added) (Exhibit B).

<sup>16</sup> See, e.g., Deposition of Laura Thoma at 226:22-228:8 (probing as to sufficiency of 15-minute cycle) (Exhibit C).

<sup>17</sup> The NECC indictment explains that Barry Cadden, et al. failed to "properly sterilize drugs in violation of USP-797" because drugs were "routinely autoclaved for a period of 15 to 17 minutes in duration, less than the 20-minute duration identified in NECC's formulation worksheets for specific drugs and USP-797." See Indictment, *U.S. v. Cadden*, No. 1:14-cr-10363-RGS [Docket #1] at 13.

<sup>18</sup> See Guardino Report at 3.

The complete about-face of the PSC is now attempting to exonerate every settled defendant, including NECC and the Insider Defendants, can only be explained by the fact that the settlements will not directly reduce the exposure of the remaining healthcare defendants.<sup>19</sup> So, the PSC is attempting to litigate a windfall, where wrongdoers who paid millions of dollars to their clients to settle their share of liability are not allocated any fault at trial. Such a result would hardly “achieve justice.”<sup>20</sup> And the PSC’s new stance puts the PSC directly at odds with the United States government’s prosecution of NECC in the criminal trial. The PSC will be arguing in the civil trials for the *smallest* allocation of fault possible to NECC and the Insider Defendants (asserting the evidence against them cannot even meet the “preponderance of the evidence” standard) while the United States will be arguing that NECC’s fault is so great, its principals should be convicted of federal crimes (under the much higher, “beyond a reasonable doubt” standard). At the same time, the Saint Thomas Entities will be agreeing with the United States that NECC’s actions were not only criminal, but the sole and intervening cause of all damage to the Bellwether Plaintiffs.

Because the PSC now has the perverse incentive to defend the actions of NECC and the other wrongdoers who contributed to the contamination of the steroids, permitting any civil trial to occur before the criminal trial creates a significant risk of negatively impacting the criminal prosecution. No good can come from a judgment in a civil trial based on a causation theory that

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<sup>19</sup> There will be no settlement credit for amounts paid by settling parties; instead, the jury allocates fault between the defendants and responsible parties designated by defendants (*e.g.*, settled parties). *Williams Holding Co. v. Willis*, 166 S.W.3d 707, 712 (Tenn. 2005). The jury is entitled to hear about the prior settlements and claims of fault by the PSC in order to allocate fault. *See Kennon v. Slipstreamer, Inc.*, 794 F.2d 1067, 1070 (5th Cir. 1986) (explaining that a jury may be told of the existence of a settlement in order to avoid jury confusion as to the absence of the settled party from trial).

<sup>20</sup> Lawyers for victims of the outbreak said the agreement marked a significant step forward. “The plaintiffs steering committee and others have worked hard to hold *the wrongdoers accountable*,” said Nashville attorney Mark Chalos, calling the [UniFirst] settlement “another step toward *achieving justice*.” *See* “Fund for Meningitis Victims Jumps by \$30.5 Million,” available at [http://meningitis-etc.blogspot.com/2015\\_02\\_01\\_archive.html](http://meningitis-etc.blogspot.com/2015_02_01_archive.html) (last visited 3/31/2016) (emphasis added).

is inconsistent with the position the United States intends to take in the criminal trial. And until the criminal trial occurs, no one will not know how the criminal prosecutors will prove causation or the evidence they have on causation as a result of their searches and seizures at NECC.

**D. The Criminal Discovery Is Needed For Fair Adjudication of Civil Liability**

The Nashville Healthcare Defendants will suffer significant hardship if they are forced to trial prematurely without the discovery they cannot obtain until after the criminal trial. That discovery is highly relevant to these civil cases because it concerns the cause of the contamination at NECC and STOPNC's defense that it was not negligent in purchasing from NECC.<sup>21</sup> *See, e.g.*, Docket #2275 at 3-7; *see also* part II.A & D. More recent developments in the discovery phase illustrate the extent of the prejudice to these defendants.

For example, when the FBI and other federal agencies raided NECC in 2012, they seized much evidence, including various medical stock and supplies.<sup>22</sup> The government has presumably tested these materials and will use the results of such tests in connection with the criminal prosecution. The Saint Thomas Entities' have been denied access<sup>23</sup> and so are unable to conduct any such testing. The PSC is using this lack of access to argue that the Saint Thomas Entities' experts have not conducted enough testing. The PSC's new expert states:

I have seen no evidence that *definitively establishes* when, how or where the contamination of NECC's MPA product occurred. Given the passage of time and

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<sup>21</sup> As the Court is aware, the Saint Thomas Entities did not inject any of the Tennessee patients with the NECC-compounded steroids, but have been sued based on their corporate relationship to STOPNC. If STOPNC is not liable to the Tennessee Plaintiffs, the Saint Thomas Entities cannot be liable to them.

<sup>22</sup> *See* Memorandum in Support of Saint Thomas Entities' Motion to Compel Invoking Defendants to Produce Certain Documents [Docket #2118].

<sup>23</sup> *See, e.g.*, Order denying Motion to Compel [Docket #2240] (denying the Saint Thomas Entities access to the criminal discovery produced to Barry Cadden, et al.); Electronic Order granting Government's Motion to Stay [Docket #2556] (precluding the Saint Thomas Entities from deposing witnesses until conclusion of the first criminal trial).

the lack of empirical evidence required to draw such a conclusion, *it may never be known* how and when the contamination occurred.<sup>24</sup>

The PSC has also tried to impeach experts for not talking to state and federal officials about the case, all the while knowing this Court has precluded the defendants from access to the fruits of the criminal investigation and the FDA.<sup>25</sup> The PSC has even suggested federal law enforcement somehow contaminated the scene.<sup>26</sup> The PSC's attempt to accuse the government investigators of altering evidence reveals both the lengths to which it will go to defend the settling wrongdoers and the inextricable intertwinement of the civil and criminal cases.

Further, NECC's process for compounding MPA was only partially documented, and the available evidence reveals that NECC in practice deviated from even its partial documentation. But the only people who can testify as to how NECC actually compounded MPA are beyond the reach of the Saint Thomas Entities until after the criminal trial. *See* part II.A. They will not have any of the e-mails from the personal account of Glenn Chin, the pharmacist who compounded the contaminated MPA.<sup>27</sup> The PSC again tries to take advantage of this lack of access. It has tried to impeach defense expert witnesses by asking them questions about NECC's operations at a level of detail only someone like Joe Connolly could answer. The following exchanges occurred at the deposition of compounding pharmacist David Joseph:

Q: And do you know if the location of that hood had changed between May, June, and August of 2012 and December of 2012?

A. That's something that I would not have information on.

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<sup>24</sup> *See* Guardino Report at 3 (emphasis added).

<sup>25</sup> Deposition of K. St. John at 150:25-151:3 (Exhibit D).

<sup>26</sup> *See id.* at 149:24-150:13; *see also* Deposition of Ray Schneider, P.E. at 164:19-165:10 (Exhibit E).

<sup>27</sup> The government obtained Chin's personal e-mails from AOL and produced them to criminal defense counsel by letter dated February 12, 2015. *See* Memorandum in Support of Saint Thomas Entities' Motion to Compel Invoking Defendants to Produce Certain Documents [Docket #2118] & Exhibit B [Docket #2118-2].

Q: And how many hoods were used to prepare – was it only one hood that was used to prepare the three contaminated lots, the May lot, the June lot, and August lot of MPA?

A. That, I don't know specifically....

Q: Do you know which hood each lot was prepared in?

A. I do not.<sup>28</sup>

As demonstrated by these depositions, the PSC, in its attempt to defend NECC and minimize the jury's allocation of fault to NECC (whose owners have already paid into the Tort Trust Fund), will attempt to impeach defense experts at trial for not having access to the very evidence that the Nashville Healthcare Defendants have repeatedly but unsuccessfully attempted to obtain.<sup>29</sup> Only after the criminal trial will the Saint Thomas Entities likewise have key evidence—like Mr. Connolly's testimony and the other evidence the government seized from NECC—to show not only who is at fault for the contamination, but the extent of such fault and how the contamination happened. The government has promised as much:

The government submits that *the trial in this case will reveal overwhelming evidence* of the two defendants' extreme recklessness and wanton and willful disregard for human life that *directly caused the deaths* of the twenty-five individuals named in the Indictment....

Every one of these 25 deaths would not have occurred *but for* the defendants' extreme recklessness. *This was not an unfortunate unexplainable tragedy; this was murder.*<sup>30</sup>

If the evidence the government alone has establishes that Barry Cadden and Glenn Chin committed second-degree murder as to these victims, then the juries in the civil cases are entitled to know that when allocating fault between NECC and anyone else, including the settling parties. The Saint

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<sup>28</sup> See Deposition of David Joseph at 27:20-28:4; 29:1-3; 265:22-266:5 (Exhibit F).

<sup>29</sup> See Electronic Order granting Government's Motion to Stay [Docket #2556].

<sup>30</sup> See Government's Opposition to Defendants' Motion to Dismiss Count 1 (RICO) and Count 2 (RICO Conspiracy), and to Strike Murder Racketeering Acts From Count 1, *U.S. v. Cadden*, No. 1:14-cr-10363-RGS [Docket #456] at 15-16 (emphasis added).



Thomas Entities have previously indicated that their experts would be hampered without the evidence that will only be available after the criminal trial.<sup>31</sup> Discovery to date proves them right.

**E. Trying the Criminal Case First Eliminates Both the Risk to the Government and Prejudice to the Saint Thomas Entities**

Discovery from the NECC Witnesses was stayed to avoid prejudice to the government, which plans to use the same witnesses at the criminal trial.<sup>32</sup> Once the criminal case is tried, there will no longer be any risk to the government's or criminal defendants' ability to present their cases. As the Department of Justice put it, "Allowing the criminal trial to proceed first would likely obviate the need for most if not all of the depositions the Saint Thomas Entities now seek. To the extent they need additional testimony beyond what is elicited in the criminal trial, they can seek it following the criminal trial in a more streamlined and efficient way."<sup>33</sup>

The evidence against NECC and Insiders and the evidence from the criminal trial will be essentially prepackaged, making the civil trials more efficient. *See Rosenthal v. Giuliani*, No. 98 Civ. 8408(SWK), 2001 WL 121944, at 2 (S.D.N.Y. Feb. 9, 2001) (staying civil proceedings in part based on finding that "a stay ... will streamline later civil discovery since transcripts from the criminal case will be available to the civil parties).

Conversely, if the Court proceeds with setting the civil bellwethers as announced, the last two trials will occur in September and October, with the civil and criminal proceedings going forward at the same time and at the same courthouse, down the hall from each other. It would create special challenges for the civil defendants in that they will be defending themselves in one courtroom while simultaneously trying to collect evidence from the criminal trial taking place in another courtroom. These risks and burdens are avoided by sequencing the criminal trials first.

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<sup>31</sup> *See* Docket #2275 at 6.

<sup>32</sup> Electronic Order granting Government's Motion to Stay [Docket #2556].

<sup>33</sup> Docket #2209 at 16.

**F. The Public Interest and Judicial Economy Are Served by Sequencing the Criminal Trial First**

The government’s trial includes dozens of alleged *crimes* committed against these Tennessee Plaintiffs and many others—resulting in the deaths of at least 64 individuals and suffering of close to 700 others, as charged in the indictment. The government has indicated that its criminal trial is “one of the highest priorities of the [U.S. Attorney’s Office]” and “one of the most significant federal prosecutions currently ongoing in the United States.” Docket #1838-3 ¶ 5. The investigation resulting in a 131-count indictment against 14 of the Insider Defendants “is being conducted by the [FDA] Office of Criminal Investigations (‘FDA-OCI’); the Federal Bureau of Investigation; the Department of Veterans Affairs, Office of Inspector General; the Department of Defense, Defense Criminal Investigative Service; and the United States Postal Inspection Service.” *Id.* And the government has been able to use search warrants and other exclusive means to obtain “more than 760,000 pages of documents from NECC; “electronic media containing NECC’s email, financial, and operational records;” and “numerous physical items,” including “compounded drugs in bulk form; compounded drugs packaged in vials, syringes, bottles, and bags; drug ingredients; lab materials; lab equipment; packaging materials; and surveillance videos.” Docket #1838-3 ¶ 6. This investigation and criminal proceeding affects all of the 751 patients in 20 states reported by the U.S. Centers for Disease Control to have suffered from fungal infections as a result of NECC’s wrongdoing, Docket #1838-3 ¶ 4—not just the MDL Plaintiffs.

The Bellwether Plaintiffs, by contrast, were selected from a pool of 108 Tennessee patients whose cases have been developed for trial on a faster track than others in the MDL. No one has claimed that these bellwether cases are representative of the hundreds of other cases involved in the criminal case. In fact, as a result of settlements and the confirmation of NECC’s bankruptcy plan, these cases no longer include any of the NECC Insiders or National Defendants as parties; they involve only Tennessee parties and Tennessee claims. And thus far, the discovery tools

available to the Nashville Healthcare Defendants—as limited by protective orders relating to the criminal proceeding, the bankruptcy, and the mediation program conducted by the PSC—have permitted them to develop only limited facts about NECC and the FDA’s role in the outbreak.

Public interest strongly favors the government’s case going first:

The very fact that there is a clear distinction between civil and criminal actions requires a government policy determination of priority: which case should be tried first. Administrative policy gives priority to the public interest in law enforcement. This seems so necessary and wise that a trial judge should give substantial weight to it in balancing the policy against the right of a civil litigant to a reasonably prompt determination of his civil claims or liabilities.

*Campbell v. Eastland*, 307 F.2d 478, 487 (5th Cir. 1962); *see also See Bridgeport Harbour Place I, LLC v. Ganim*, 269 F. Supp. 2d 6, 10 (D. Conn. 2002) (“The public interest will be served best by allowing the government’s case to proceed without obstacles.”); *Rosenthal v. Giuliani*, No. 98 Civ. 8408(SWK), 2001 WL 121944, at \*2 (S.D.N.Y. Feb. 9, 2001) (“The public has an interest in ensuring the criminal process is not subverted.”).

For similar reasons, sequencing the criminal trial before the civil trial promotes judicial economy. *See In re Worldcom, Inc.*, No. 02 Civ. 3288(DLC) & 02 Civ. 4816(DLC), 2002 WL 31729501, at \*8 (S.D.N.Y. Dec. 5, 2002) (“The conviction of a civil defendant as a result of the entry of a plea or following a trial can contribute significantly to a narrowing of issues in dispute in the overlapping civil cases ....”); *see also Rosenthal*, 2001 WL 121944, at \*2 (noting that the transcripts from the criminal trial would “streamline later civil discovery”).

#### **G. This Request Is Made in Good Faith**

The First Circuit also includes “the good faith of the litigants (or the absence of it)” as a consideration. *Microfinancial*, 385 F.3d at 78. Here, there can be no question that the Saint Thomas Entities make this request in good faith. They are not the criminal defendants, and they seek a brief stay solely because they cannot access the proof necessary to defend themselves despite considerable efforts to do so. Their inability to obtain evidence from the criminal

defendants cannot be attributed to any action or inaction by these defendants. And they have been diligent in developing these cases for initial trials despite the discovery bars.

#### **H. The Status of the Cases Favors Deferral**

Finally, the respective statuses of the criminal and civil cases militates strongly in favor of trying the criminal case first. Since “courts are more likely to grant stays when an indictment has already been issued, as is the case here,” *Rosenthal*, 2001 WL 121944, at \*2; *see also Worldcom*, 2002 WL 31729501, at \*4, the Court should be even further encouraged to do so where the criminal trial is ready to begin in just a few months. In fact, the criminal case is set for September 8, and the civil trials have not yet been set, nor are they in a procedural posture to be set at this time. *See* part I. Moreover, the parties can continue to prepare the bellwether cases for trial during the time the criminal case is underway, and the evidentiary fruits of that trial will be immediately available to streamline the factual presentation of the civil trials and afford the defendants a full and fair opportunity to present the jury with the whole picture of what happened. *See* part II.B & E. Any other approach denies defendants the ability to properly prepare and present their defense. The totality of the circumstances compels the conclusion that the criminal trial should proceed first.

### **III. The Bellwether Schedule Proposed by the Court Is Overly Ambitious**

#### **A. There Is Not Enough Time for Ruling on *Daubert* and Case-Specific Dispositive-Motion Challenges**

Under the current schedule, the deadline for filing *Daubert* motions is May 27, and those motions will not be ripe for consideration until the June 23 status conference at the earliest. The deadline to seek leave to file case-specific dispositive motions is May 18. *See* Docket #2596 at 2. The dispositive motions themselves can only be filed after leave is granted, *id.*, so these motions may not even be eligible for consideration by the June 23 status conference.

#### **B. Neither the Court Nor the Parties Can Accommodate Four Back-to-Back Bellwether Trial Settings**

The Saint Thomas Entities anticipate that the first individual bellwether trial will take up

to six weeks of half days and at least three full weeks to try. Even with strict limitations on trial presentations, these bellwether cases will require numerous witnesses, considering the complexity of the issues and number of parties. Although the Court previously indicated that “nearly all of the evidence presented to the jury will be documentary,” Docket #2309 at 23, that is simply not the case. *See* part I.B. As outlined above in parts I-II, trial of these cases will involve numerous fact and expert witnesses who will likely be questioned by all parties. The Court should not unduly restrict the parties from making full presentations of their cases—especially when considering the bellwether nature and implications of these initial trials. Taking into account the significant amount of pretrial preparation needed for each case, these four bellwether cases cannot be tried to completion over a series of four months and will overlap substantially—which is not feasible—if the cases are tried on a 9 am to 1 pm schedule.

**C. Both Common-Issue and Case-Specific Discovery Is Ongoing**

There is still much to be done to complete discovery before trial preparations can begin. The parties have until April 9 to complete common expert depositions, Docket #2715, and will need every day of that period, considering the number of experts that have been designated by both sides. And May 6 is the current deadline for case-specific fact and expert discovery, which is underway on a very ambitious deposition schedule. Docket #2596 at 1. Exhibit G details the work to be completed. There are at least 19 Common-Issue and Case-Specific Experts and 9 fact witnesses left to be deposed, and these numbers may increase significantly based on the Nashville Healthcare Defendants’ respective case-specific expert disclosures and additional fact-witness depositions requested by the parties. The parties have worked at a feverish pace to complete this discovery, often taking more than one deposition in a single day and scheduling them on the weekends. But it is simply impossible to complete all of this work and simultaneously prepare for four, back-to-back jury trials beginning in July.

#### IV. The Tennessee Court Should Make any Trial Settings

##### A. Recent Developments Confirm These Cases Should Be Tried in Tennessee

The Court has previously ruled against the Saint Thomas Entities' arguments that § 157(b) is no longer available to support trial venues here as a result of the confirmation of the bankruptcy plan, which greatly reduced, if not eliminated, its "related to" bankruptcy jurisdiction, Docket ##2090, 2309, and they will not restate them here. Since that time, case developments further show why the Court should decline to try these cases in Massachusetts even if it has the authority to do so under the Bankruptcy Code. First, the bankruptcy Plan has long since been confirmed, removing all vestiges of bankruptcy from the tort cases. Common-issue fact discovery is over, and no discovery from the PCO has occurred in months. That some limited discovery theoretically may be permitted against NECC does not support a Boston trial of cases that belong in Tennessee.

Second, the Court's rulings on choice of law and comparative fault confirm that Tennessee, not Massachusetts law, governs the claims and defenses to be tried. Docket #2581. It recognized that Tennessee has far greater interests than Massachusetts "in adjudicating disputes between its residents concerning injuries that occurred within its borders." *Id.* at 6.

The manifest purpose of § 157(b)(5)—"to centralize the *administration of the estate* and to eliminate the 'multiplicity of forums for the adjudication of *parts of a bankruptcy case*'"<sup>34</sup>—is lacking here. The civil cases no longer have any meaningful connection to what little remains of the bankruptcy or to Boston.

##### B. The § 157(b)(5) Considerations Weigh in Favor of Sending These Cases Back to Tennessee for Trial

There is no concern of any "multiplicity of forums" here. *All* of the MDL tort cases

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<sup>34</sup> *A.H. Robins Co., Inc. v. Piccinin*, 788 F.2d 994, 1011 (4th Cir. 1986) (quoting 130 Cong. Rec. H7492 (June 29, 1984) (remarks of Congressman Kastenmeier), *reprinted in* 1984 U.S.C.A.A.N. at 579) (emphasis added); *see also Lindsey v. O'Brien, Tanski, Tanzer & Young Health Care Providers of Conn. (In re Dow Corning Corp.)*, 86 F.3d 482, 496 (6th Cir. 1996).

involving Tennessee Plaintiffs can be transferred to Tennessee (even those filed in Massachusetts and any transferred originally under § 157(b)(5)). *See* 28 U.S.C. § 157(b)(5).

That result is consistent with *Lexecon*, which upheld Congress’ statutorily explicit intent that cases transferred for the purpose of pretrial coordination under § 1407 be sent back to their originating courts for trial absent a waiver of venue by all parties. *See Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 40-41 (1998).

It also comports fully with the factors to be considered under § 157(b)(5) in determining the best trial venue. The probable impact on the bankruptcy proceeding resulting from claims resolution in a consolidated venue against issues of comity, respect for the application of state law, location and convenience of the parties, and deference to the plaintiffs’ original choice of forum all favor Tennessee. *See In re Pan Am Corp.*, 950 F.2d 839, 844 (2d Cir. 1991) (“[S]ection 157(b)(5) has consistently been construed to recognize discretion in district courts to leave personal injury cases where they are pending.”); *see also* part IV.A.

The federal courts in Tennessee are very familiar with Tennessee law, and to the extent there are any remaining unsettled questions of Tennessee law, the federal district courts there can certify those questions to the Tennessee Supreme Court for resolution. *See* TENN. SUP. CT. R. 23, § 1 (“The Supreme Court may, at its discretion, answer questions of law certified to it by ... a District Court of the United States in Tennessee, ...”). The U.S. Court for the Middle District of Tennessee was the choice of forum for almost all of the Tennessee Plaintiffs, and there is little question that Tennessee is most convenient to the parties and witnesses. The locus of operative facts is Tennessee, as the entire relationship between the parties is centered in Tennessee, and the injections and claimed injuries occurred there.

It makes no sense to try Tennessee-centric matters to a Boston jury. Nor is it fair to burden this District with dozens of cases where the plaintiffs and defendants are citizens of another state.

### CONCLUSION AND PRAYER

For these reasons, the Saint Thomas Entities request that the Court:

(i) stay all proceedings after the *Daubert* deadline until ten days after a verdict or plea agreement is reached in *U.S. v. Cadden*;

(ii) permit the Saint Thomas Entities to depose Joe Connolly, John Notarriani and any other NECC witness within 30 days after a verdict or plea agreement is reached in *U.S. v. Cadden*; and

(iii) allow the Saint Thomas Entities to amend their expert reports relating to causation within 30 days of completing the post-criminal trial NECC discovery.

If the Court does not stay proceedings pending the criminal trial, the Saint Thomas Entities request in the alternative that the Court:

(i) suggest a remand of the four bellwether cases to the JPML at the conclusion of the pretrial proceedings (or transfer them under § 1404(a)) so they can be tried in Tennessee; and

(ii) refrain from setting any trials until after remand to Tennessee and no earlier than 30 days after a decision is made as to whether to retransfer the cases back to Massachusetts for trial.

If the Court does not follow this course, the Saint Thomas Entities request in the alternative that the Court:

(i) reconsider its prior discovery rulings related to the NECC Insiders and FDA to allow them to depose those individuals;

(ii) rule on the jurisdictional and venue issues addressed above and enter an order by the May status conference clearly setting trial dates in order to allow for pretrial arrangements;

(iii) enter clear trial settings so the parties may adequately prepare; and

(iv) grant such other and further relief to which the Saint Thomas Entities are entitled.



Dated April 4, 2016

SAINT THOMAS WEST HOSPITAL,  
FORMERLY KNOWN AS ST. THOMAS  
HOSPITAL, SAINT THOMAS  
NETWORK, AND SAINT THOMAS  
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**CERTIFICATE OF SERVICE**

This certifies that a true and accurate copy of the foregoing was served on all parties of record by virtue of the Court's electronic filing system this 4th day of April, 2016.

/s/ Sarah P. Kelly  
SARAH P. KELLY